

**3745. Misbranding of phenobarbital tablets and pentobarbital sodium capsules.** U. S. v. Joseph P. Cataldo (Winton Pharmacy), and Derwent William McCann. Pleas of guilty. Fine of \$500 against Defendant Cataldo and \$250 against Defendant McCann. (F. D. C. No. 32743. Sample Nos. 6760-L, 6767-L, 6769-L, 7762-L, 7763-L.)

**INFORMATION FILED:** March 31, 1952, Western District of New York, against Joseph P. Cataldo, trading as the Winton Pharmacy, Rochester, N. Y., and Derwent William McCann, a pharmacist employed by Joseph P. Cataldo.

**ALLEGED VIOLATION:** On or about February 12 and March 12, 1951, while a number of the *phenobarbital tablets* and *pentobarbital sodium capsules* were being held for sale at the Winton Pharmacy after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *phenobarbital tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

**DISPOSITION:** May 26, 1952. Pleas of guilty having been entered, the court imposed a fine of \$500 on each of the 2 counts of the information against Defendant Cataldo and a fine of \$250 on each of the 2 counts against Defendant McCann, after which the court suspended the fines which had been imposed against the defendants on count 2 of the information.

**3746. Misbranding of Donnatal tablets and sulfadiazine tablets.** U. S. v. Dewberry Drug Co., Ltd., Milton Temerson, Walker N. Fricks, Grafton G. Smith, and James O. Self. Pleas of *nolo contendere*. Fine of \$50 against each defendant. (F. D. C. No. 31287. Sample Nos. 75113-K, 752-L, 21403-L, 21424-L to 21426-L, incl.)

**INFORMATION FILED:** December 19, 1951, Northern District of Alabama, against Dewberry Drug Co., Ltd., a partnership, Birmingham, Ala., and against Milton Temerson, a partner in the partnership, and Walker N. Fricks, Grafton G. Smith, and James O. Self, pharmacists for the partnership.

**INTERSTATE SHIPMENT:** From the States of Virginia and Missouri into the State of Alabama, of quantities of *Donnatal tablets* and *sulfadiazine tablets*.

**ALLEGED VIOLATION:** On or about September 7, 1950, and January 17, March 8, and May 5 and 7, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The partnership and Milton Temerson were charged with causing the acts of repacking and dispensing of the drugs involved in each of the 6 counts of the information. In addition, Walker N. Fricks in 1 count, Grafton G. Smith in 1 of the other counts, and James O. Self in 1 of the 2 other counts were charged with causing the acts involved in those counts.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (2), the repackaged *sulfadiazine tablets* failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Donnatal tablets* contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *Donnatal tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *Donnatal tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, as are necessary for the protection of users.

**DISPOSITION:** January 10, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of \$50 against each of the defendants.

**3747. Misbranding of Vitoplus capsules, vitamin A capsules, vitamin B complex capsules, and d-alpha-tocopheryl acetate capsules. U. S. v. 115 Bottles, etc. (F. D. C. No. 32022. Sample Nos. 9902-L, 9903-L, 9905-L to 9907-L, incl.)**

**LIBEL FILED:** November 23, 1951, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about August 21, September 21, and October 5, 1951, from Detroit, Mich., by the Gelatin Products Div., R. P. Scherer Corp.

**PRODUCT:** 115 100-capsule bottles of *Vitoplus capsules*, 1 15,000-capsule box and 49 50-capsule bottles of *vitamin A capsules*, 156 100-capsule bottles of *vitamin B complex capsules*, and 139 100-capsule bottles of *d-alpha-tocopheryl acetate capsules* at Chicago, Ill., together with a number of booklets entitled "Healthway Products Almanac 1951."

**RESULTS OF INVESTIGATION:** All of the products originally were shipped in bulk, and those products contained in the bottles represented the portions of the products which had been repackaged by the consignee, the Illinois Herb Co., Chicago, Ill. The booklets which are referred to above were printed locally and were to be sent by mail to prospective customers.

**LABEL, IN PART:** (Bottle) "100 Vitoplus No 59 Capsules Ingredients in each capsule: Liver Desiccated - 200 mg. Ferrous Sulfate, Dried USP - 136.1 Mg. (Equivalent to 40 mg. of iron) Thiamin Hydrochloride USP - 1 mg. Riboflavin USP - 2 mg. A fermentation extract equivalent in microbiological potency to Vitamin B<sub>12</sub> - 1 microgram."